

REMARKS

Claims 1, 2 and 4-31 are active. No claim amendments have been made. The claims are re-presented above for the convenience of the Examiner. No new matter has been added.

Rejections based on Yu., JP63-126542

The prior art rejections below are all based on Yu, JP63-126542. Yu is concerned with emulsions produced by selecting oils (not surfactants) having particular “inorganic characteristics” (page 5, line 11-*et seq.*) and does not render the present invention obvious, because it does not disclose or suggest (1) selecting a ratio of oily component to surface active agent of 11.67 or above, and (2) selecting a surface active agent having a dynamic surface tension of 57 mN/m or less. Both of these limitations must be considered together since obviousness requires consideration of the invention as a whole, see MPEP 2141.02:

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.* 218 USPQ 871 (Fed. Cir. 1983; *Schenck v. Nortron Corp.*, 218 USPQ 698 (Fed. Cir. 1983)).

The claims require that the ratio of the oily component to the surface active agent in the emulsion be greater than 11.67:1 (see Claim 1) and that the surface active agent have a dynamic surface tension of 57 mN/m or less. That is, the emulsions must contain at least 11.67 more oily component than surface active agent and the surface active agent must have a low dynamic surface tension. By using this combination of a high ratio of oily component to surface active agent and a surface active agent with a low dynamic surface tension, the

inventors have found that highly transparent and stable emulsions can be formed (see Tables 1, 2 and 3 in the specification). Thus, the present invention overcomes the known prior art problem of providing a transparent and stable emulsion that contains a lot of oil and a little surfactant. The cited prior art itself acknowledges the difficulty of incorporating large quantities of oil into an emulsion using only a small amount of a surface active agent. Too much oil relative to the surface active agent leads to hydrophilic-lipophilic phase imbalance resulting in opacity of the emulsion and then separation of the emulsion into its oil and water phases (see e.g., Yu, translation, page 3, lines 1-4).

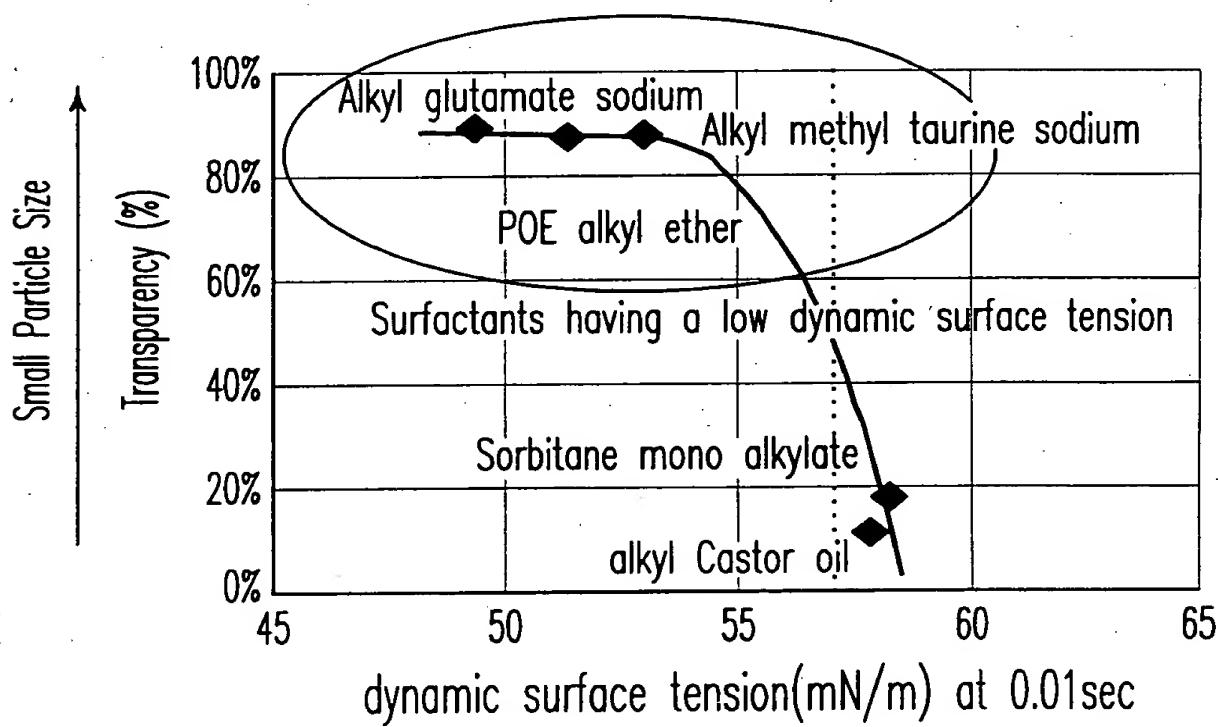
Yu discloses emulsions having a ratio of surface active agent to oily component of 0.5:1 to 10:1 (page 4, line 13 and page 7, line 3) and place little or no restrictions on the identities of the generically-defined surfactants (Yu, page 3, fourth to last line: “ordinary ionic surfactant”) The upper limit disclosed by Yu is 10 parts oily component to one part surfactant. Absence evidence of criticality, the Official Action regards the ratio of at least 11.67 :1 required by the present claims to be an obvious variant of the upper end of the range disclosed by Yu: 10: 1. However, as noted above, the question is not whether each individual limitation is itself obvious, but whether the cited prior art suggests the invention as a whole.

To suggest the invention as a whole, Yu must suggest making an emulsion having at least 11.67 parts oily component to surface active agent and suggest that the surface active agent have a dynamic surface tension below 57 mN/m. Yu fails to suggest this combination

or the superior transparency and stability it provides, and therefore cannot render the invention as a whole obvious.

On the other hand, the Applicants have already shown the criticality of selecting a surface active agent having a dynamic surface tension value of 57 mN/m for obtaining highly transparent and stable emulsions having high oily component content--see Tables 1-3 in the specification and Table 2 below which is reproduced from the Declaration submitted July 16, 2004.

Table 2



As shown, the transparency of emulsions produced using surface active agents with dynamic surface tension values above 57 mN/m is low, generally less than 20%. On the other hand, the transparency of emulsions produced using surface active agents having dynamic surface tension values less than 57 mN/m is high—above 80%.

Furthermore, the Declaration attached to this Amendment provides further comparisons of the prior art emulsions of Yu and those of the invention. When three of the emulsions exemplified by Yu in Examples 28, 31 and 32 were reformulated to contain an oil: surfactant ratio approximating the lower end of the ratio required by the invention (11.67:1), these emulsions exhibited virtually no transparency. On the other hand, the emulsions of the present invention as shown in Examples 1 and 11 have high transparency (87.8% or 80.2%) at these high ratios of oil: surfactant (i.e., at 12.6 or 20.2 to 1). Accordingly, the Applicants respectfully submit that Yu does not disclose or suggest the invention as a whole, nor does it provide a reasonable expectation of success for obtaining stable and transparent emulsions when the amount of the oily component at least 11.67 more than the amount of surfactant. Therefore, all the rejections based on Yu should be withdrawn. Each rejection based on Yu is individually discussed below.

Rejection--35 U.S.C. 103

Claims 1, 2, 6-8, 10-21, 27-29 and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542. Yu does not render the present claims obvious because there is no disclosure or suggestion of a ratio of B:A of more than 11.67:1. The uppermost part of the ratio disclosed by Yu is “up to 10” parts oil to surfactant.

The Examiner regards 10:1 as the equivalent of 11.67: 1 without evidence of criticality. As discussed above, the present inventors have shown the criticality of selecting the combination of a high oil: surface active agent ratio and a surface active agent having a low dynamic

surface tension for producing stable and transparent emulsions. Yu teaches away from this combination by specifying an upper limit of 10: 1, by indicating the difficulty in producing stable emulsions when high amounts of oil are used and by indicating that any “ordinary ionic surfactant” may be used.

Yu does not envisage or suggest selecting of a surface active agent having a dynamic surface tension of 57 mN/m or less for the production of an emulsion wherein the ratio of the oily component (B) is more than 11.67 based on 1 of the surface active agent (A). Dynamic surface tension is not disclosed by Yu at all and is not the equivalent of the “inorganic characteristics (page 5, line 11) disclosed by Yu, which apply to oils selected to make the emulsion and not to the surface active agent. Yu makes emulsions by selecting a particular type of oil. The present invention requires the selection of a particular type of surfactant.

Yu, see e.g. page 7, lines 1-3, is broadly directed to emulsions produced with various ratios of ingredients and does not suggest that stable, highly-transparent emulsions could be produced using a ratio of at least 10 parts oily component to 1 part of surface active agent. Specifically, Yu does not suggest that such emulsions could be produced by selecting a surface active agent having a dynamic surface tension of 57 mN/m or less.

Moreover, Yu does not provide a reasonable expectation of success in obtaining emulsions with the superior properties of those of the invention, such as superior transparency. Selection of a surface active agent with a dynamic surface tension of 57 mN/m, provides an emulsion with superior properties, such as very high transparency, see Table A below.

TABLE A

surface active agent	dynamic surface tension	Transparency
lauroyl glutamate sodium	49.6 mN/m	>80%
POE lauryl ether	51.6 mN/m	>80%
N-lauroyl methyl taurine sodium	53.3 mN/m	>80%
lauryl Castor oil	58.0 mN/m	<20%
sorbitane monolaurlylate	58.4 mN/m	<20%

As shown in Table A above, oil-in-water emulsions produced using a surface active agent having a dynamic surface tension of 57 mN/m or less (**embolded**), produce highly transparent emulsions, e.g. emulsions having a transparency above 80%. On the other hand, emulsions produced with surface active agents having a dynamic surface tension above 57 mN/m exhibited less than 20% transparency. Emulsions with high transparency are desirable in many applications, such as in cosmetics.

The Official Action indicated that the data in the Declaration were not persuasive because the data were not commensurate in scope with the claims. The Applicants disagree as the claims are clearly limited to emulsions produced by selecting a surface active agent having a dynamic surface tension of 57 mN/m or less. The Declaration shows precisely this: that selection of a surface active agent having a dynamic surface tension of 57 mN/m or less produces a highly transparent emulsion as shown by a representative number of such surface

Appl. No. 09/842,161

Reply to Official Action of September 9, 2005

active agents. The emulsions produced with the surface active agents required by the present invention each had transparency above 80%. On the other hand, comparative surface active agents not having a dynamic surface tension of 57 mN/m or less did not, producing emulsions having less than 20% transparency. Accordingly, the Applicants respectfully submit that the data of record clearly are commensurate in scope with the claims and demonstrate the superior properties of the emulsions of the present invention.

Therefore, as the prior art does not envisage or suggest the stable high-oily component emulsions of the invention that use a surface active agent with a dynamic surface tension of 57 mN/m or less, or disclose or suggest the superior properties of such emulsions, the Applicants respectfully request that this rejection be withdrawn.

Rejection--35 U.S.C. 103

Claims 4, 5 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of Drapier et al., U.S. Patent No. 6,121,228. Drapier is directed to liquid cleaning compositions that contain less than 10 parts of oily substance to 1 part surfactant and Draper does not suggest producing emulsions by selecting a surface active agent having a dynamic surface tension of 57 mN/m or less. This rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

Appl. No. 09/842,161
Reply to Official Action of September 9, 2005

Rejection--35 U.S.C. 103

Claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of Ansel, Pharmaceutical Dosage Forms and Drug Delivery Systems. This rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

Rejection--35 U.S.C. 103

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of Gers-Berlag et al., U.S. Patent No. 5,876,702. This rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

Rejection--35 U.S.C. 103

Claims 23 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of Diec et al., U.S. Patent No. 6,468,551 B1. This rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

Rejection--35 U.S.C. 103

Claims 24 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8, 10-21, 26 and 27

Appl. No. 09/842,161
Reply to Official Action of September 9, 2005

above, and further in view of Brunetta et al., U.S. Patent No. 5,562,911. The Applicants submit that this rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

Rejection--35 U.S.C. 103

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8, 10-21, 26 and 27 above, and further in view of Shiojima et al., U.S. Patent No. 6,066,316. This rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27. Moreover, Shiojima does not disclose an emulsion having an average particle size ranging from 0.01 to 0.2 μ m and is silent about the dynamic surface tension value of POE behenyl ether. Moreover, the rejection does not address the other components in the composition of Test Example 2, which appear to be surface active agents. The composition of Test Example 2 would not meet the weight ratio limitation of Claim 1 if these components are surface active agents.

Appl. No. 09/842,161
Reply to Official Action of September 9, 2005

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Thomas M. Cunningham, Ph.D.
Registration No. 45,394

Customer Number
22850

(703) 413-3000
NFO/TMC/krs